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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO	
09/719,410	12/12/2000	Burkhard Goke	0206-UTL-9	8826	
75	590 02/07/2006		EXAM	INER	
ARNOLD & PORTER			MOHAMED, ABDEL A		
Attn: IP Docket 555 Twelfth Str	ting Departement, Room reet. NW	1126B	ART UNIT	ART UNIT PAPER NUMBER	
	C 20004-1206		1654		
			DATE MAILED: 02/07/200	6	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	plication No. Applicant(s)					
Notice of Abandones and	09/719,410	GOKE ET AL.					
Notice of Abandonment	Examiner	Art Unit					
	Abdel A. Mohamed	1654					
The MAILING DATE of this communication app		· · · · · · · · · · · · · · · · · · ·	dress				
Γhis application is abandoned in view of:							
<ol> <li>Applicant's failure to timely file a proper reply to the Office letter mailed on 30 June 2005.</li> <li>(a) ☐ A reply was received on (with a Certificate of Mailing or Transmission dated ), which is after the expiration of the period for reply (including a total extension of time of month(s)) which expired on</li> </ol>							
(b) 🗌 A proposed reply was received on, but it does not constitute a proper reply under 37 CFR 1.113 (a) to the final rejection.							
(A proper reply under 37 CFR 1.113 to a final rejection consists only of: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114).							
(c) A reply was received on but it does not constitute a proper reply, or a bona fide attempt at a proper reply, to the non-final rejection. See 37 CFR 1.85(a) and 1.111. (See explanation in box 7 below).							
(d) No reply has been received.							
2. Applicant's failure to timely pay the required issue fee and publication fee, if applicable, within the statutory period of three months from the mailing date of the Notice of Allowance (PTOL-85).							
(a) The issue fee and publication fee, if applicable, was received on (with a Certificate of Mailing or Transmission dated), which is after the expiration of the statutory period for payment of the issue fee (and publication fee) set in the Notice of Allowance (PTOL-85).							
(b) ☐ The submitted fee of \$ is insufficient. A balance of \$ is due.							
The issue fee required by 37 CFR 1.18 is \$ The publication fee, if required by 37 CFR 1.18(d), is \$							
(c) ☐ The issue fee and publication fee, if applicable, has not been received.							
3. Applicant's failure to timely file corrected drawings as required by, and within the three-month period set in, the Notice of Allowability (PTO-37).							
(a) Proposed corrected drawings were received on (with a Certificate of Mailing or Transmission dated), which is after the expiration of the period for reply.							
(b) ☐ No corrected drawings have been received.							
4. The letter of express abandonment which is signed by the attorney or agent of record, the assignee of the entire interest, or all of the applicants.							
<ol> <li>The letter of express abandonment which is signed by an 1.34(a)) upon the filing of a continuing application.</li> </ol>	attorney or agent (acting in a repres	entative capacity ui	nder 37 CFR				
6. The decision by the Board of Patent Appeals and Interference of the decision has expired and there are no allowed claim		e the period for see	eking court review				
7. 🛛 The reason(s) below:		Dr N/					
See Continuation Sheet	SUPERV	JON WEBER ISORY PATENT E	EXAMINER				
Petitions to revive under 37 CFR 1.137(a) or (b), or requests to withdraw the holding of abandonment under 37 CFR 1.181, should be promptly filed to							

Item 7 - Other reasons for holding abandonment: Applicant has not provided a receipt for a facsimile transmission of response under 37 C.F.R. 1.111 filed 9/30/05. Although, Applicant's Representative Mrs. Laurie Hill faxed the Examiner a courtesy copy of the facsimile transmission of response under 37 C.F.R. 1.111; however, the certificate of transmission under 37 C.F.R. 1.8 indicates that the response under 37 C.F.R. 1.111 was faxed to telephone number (703) 273-8300 which is a telephone number for Farm Insurance. Thus, the Office has not received a facsimile transmission of the response under 37 C.F.R. 1.111 filed 9/30/05 (See page 2 of attached courtesy copy of Fax transmission faxed on 2/1/06).



Amylin Pharmaceuticals, Inc. 9360 Towne Centre Drive San Diego, CA 92121 USA Tel (858) 552 2200 Fax (858) 552 2212 www.amylin.com

## **FAX TRANSMISSION**

If you do not receive this entire transmission, please call us immediately

To: Abdel Mohamed

From:

Hill, Laurie

Fax:

15712730955

Date:

02/01/2006

No. of Pages (including this sheet): 8

Subject:

US Appl. Serial No. 09/719,410

Notes:

Laurie L. Hill, Ph.D., J.D.
Patent Attorney
Amylin Pharmaceuticals, Inc.
9360 Towne Centre Drive
San Diego, CA 92121
phone (858) 309-7443
email laurie.hill@amylin.com

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#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. Serial No.:

09/719,410

Inventors:

Goke, et al.

Filed:

December 12, 2000

Title: GLUCAGON-LIKE PEPTIDE-1 IMPROVES BETA-CELL RESPONSE TO GLUCOSE IN SUBJECTS WITH IMPAIRED GLUCOSE TOLERANCE (AMENDED) Confirmation No.: 8826

TC/A.U.:

1653

Examiner: Mohamed, Abdel

## FACSIMILE TRANSMITTAL COVER SHEET

# Certificate of Transmission Under 37 C.F.R. 1.8

I hereby certify that the following listed correspondence in the above-referenced application is being transmitted by facsimile to Mail Stop Amendment, Commissioner for Patents, Alexandria, VA to telephone number (703) 273-8300 on this 30th day of September, 2005.

Deborah Wykes

Document

No. of Pages

Response to Office Action Under 37 CFR 1.111

6

Total number of pages transmitted (including this page):

7

NOTE: Each paper must have its own certificate of transmission, or this certificate must identify each paper submitted

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. Serial No.: 09/719,410

Inventors: Goke et al.

Filed: December 12, 2000

**Title:** Glucagon-Like Peptide-1 improves the Ability of the  $\beta$  Cell to Sense and Respond to Glucose in Subjects with

Impaired Glucose Tolerance

Confirmation No.: 8826

TC/A.U.: 1654

Examiner: MOHAMED, Abdel

# **RESPONSE UNDER 37 C.F.R. 1.111**

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria VA 22313-1450

Sir:

In response to the Office action dated June 30, 2005, Applicant respectfully submits the following amendments and remarks in connection with the above-identified application.

Amendments to the Claims are reflected in the listing of claims beginning on page 2 of this response.

Remarks begin on page 5 of this response.

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8a OR FACSIMILE TRANSMISSION UNDER 37 C.F.R. 1.8

I hereby certify that this paper (along with anything referred to as being attached or enclosed) is being facsimile transmitted to the USPTO at facsimile number (571) 273-8300, or deposited with the United States Postal Service on the date shown below with sufficient First Class postage in an envelope addressed to the Commissioner for Patents, Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

7/30/09

Date of Deposit

Signature of Person Mailing Paper

Name of Person Mailing P

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#### AMENDMENTS TO THE CLAIMS

This listing of claims replaces all prior versions and listings of claims in the application:

### **Listing of Claims:**

1-43 (cancelled)

44. (Previously presented) A method for treating an individual with impaired glucose tolerance who has not been diagnosed with non-insulin dependent diabetes mellitus (NIDDM), comprising:

administering to said individual a composition comprising an exendin, thereby treating impaired glucose tolerance.

- 45. (Previously presented) The method of claim 44 wherein the exendin is exendin 3, SEQ ID NO:7.
- 46. (Previously presented) The method of claim 44, wherein the exendin is exendin 4, SEQ ID NO:9.
  - 47. (Cancelled)
- 48. (Previously presented) The method of claim 44, wherein the step of administration is selected from the group consisting of intravenous, subcutaneous, intramuscular, intraperitoneal, injected depot with sustained release, deep lung insufflation with sustained release, buccal or patch.
- 49. (Previously presented) The method of claim 44, wherein the exendin is administered in a range of 0.005 nmol/kg to 20 nmol/kg.

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- 50. (Previously presented) The method of claim 44, wherein said composition contains an amount of the exendin effective to enhance the regularity of insulin responses, or the amplitude thereof, in reaction to changes in plasma glucose.
- 51. (Previously presented) The method of claim 44, wherein said composition contains an amount of the exendin effective to retard or arrest the loss of plasma glucose control or the development of non-insulin dependent diabetes mellitus.
- 52. (Previously presented) The method of claim 44, wherein said composition contains an amount of the exendin effective to enhance a normalization of insulin secretory patterns in impaired glucose tolerance.
- 53. (Previously presented) The method of claim 44, wherein said composition contains an amount of the exendin effective to reduce plasma insulin levels in an individual with impaired glucose tolerance.
- 54. (Previously presented) The method of claim 44, wherein said composition contains an amount of the exendin-effective to reduce insulin resistance in an individual with impaired glucose tolerance.
- 55. (Previously presented) A method for reducing a risk of cardiovascular event comprising:

administering to an individual a composition comprising an exendin, thereby reducing the risk of a cardiovascular event.

56. (Previously presented) The method of claim 55, wherein said composition contains an amount of the exendin effective to enhance the regularity of insulin responses, or the amplitude thereof, in reaction to changes in plasma glucose.

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57. (Previously presented) A method for reducing a risk of a cerebrovascular event comprising:

administering to an individual a composition comprising an exendin, thereby reducing the risk of a cerebrovascular event.

58. (Previously presented) The method of claim 57, wherein said composition contains an amount of the exendin effective to enhance the regularity of insulin responses, or the amplitude thereof, in reaction to changes in plasma glucose.

#### REMARKS

Applicants acknowledge and thank the Examiner for the allowance of claims 44-46 and 48-58 in the Office Action of June 30, 2005.

In the Office Action of June 30, 2005, claims 10, 17, 18, 22-24, 31-38 and 41 were rejected under 35 U.S.C. 102(b) and claims 10, 17, 18, 22-24, 31-34, 36-38 and 41 rejected under 35 U.S.C. 102(a) as allegedly being anticipated by Byrne et al., Diabetes, 46(Suppl 1):33A, Abst 0127, May 1997. While not agreeing to the rejection, but to speed issuance of the allowed claims, Applicants have cancelled claims 10, 17, 18, 22-24, 31-38 and 41, without prejudice to pursue the subject matter of those claims in a related application. With the cancellation of the claims, the rejection under 35 U.S.C. 102 is moot.

In the Office Action, claims 10-38 and 41 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Byrne et al., Diabetes, 46(Suppl 1):33A, Abst 0127, May 1997 in light of International Patent Application Publication No. WO 98/08531. While not agreeing to the rejection, but to speed issuance of the allowed claims. Applicants have cancelled claims 10-38 and 41, without prejudice to pursue the subject matter of those claims in a related application. With the cancellation of the claims, the rejection under 35 U.S.C. 103(a) is moot.

With this response all claims have been cancelled without prejudice except those claims that the Examiner has already determined to be allowable. Applicants therefore respectfully request issuance of a Notice of Allowance at the Examiner's earliest convenience. If the Examiner has any questions regarding the patentability of any of the remaining claims, the Examiner is encourage to call the undersigned at the telephone number below.

No fees are believed due for this submission. However, if a fee is due, the Commissioner is hereby authorized to charge payment of any fees associated with this communication, to Applicant's Deposit Account No. 010535. Additionally, the Commissioner is hereby authorized to charge payment or credit overpayment of any fees during the pendency of this application to Applicant's Deposit Account No. 010535.

INOTE: Change above deposit account language if a petition for extension is included with this response.]

Respectfully submitted, AMYLIN PHARMACEUTICALS, INC.

James E. Butler, Ph.D. [Attorney Name]
Registration No. 40,931 [Regis. No.]

Dated: 30 SEP 2005

AMYLIN PHARMACEUTICALS, INC. 9360 Towne Centre Drive San Diego, CA 92121

Telephone: 858.552.2200 Facsimile: 858.552.1936

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